4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 806

[Docket No. FDA-2019-N-1345]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration; HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the medical device reports of corrections and removals regulation to correct three inaccurate cross-references. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5518, Silver Spring, MD 20993-0002, 301-796-5837.

SUPPLEMENTARY INFORMATION: FDA is amending 21 CFR 806.1 to correct three inaccurate cross-references to ensure accuracy and clarity in the Agency's medical device regulations regarding medical device reports of corrections and removals. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the

regulation is nonsubstantive and provides only technical changes to correct inaccurate cross-references.

In the *Federal Register* of September 24, 2013 (78 FR 58821), FDA added the definition of "*Human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device*" at § 806.2(f). The addition of this definition caused the paragraphs following paragraph (f) in § 806.2 to be redesignated alphabetically. Although the definitions of the terms were correct in § 806.2, the paragraphs in § 806.1(b) cross-referenced three of the definitions (market withdrawal, routine servicing, and stock recovery) from § 806.2 based on the previous designations.

List of Subjects in 21 CFR Part 806

Imports; Medical devices; Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 806 is amended as follows:

PART 806--MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

1. The authority citation for part 806 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

2. In § 806.1, revise paragraphs (b)(2) through (4) to read as follows:

§ 806.1 Scope.

* * * * *

(b) * * *

(2) Market withdrawal as defined in § 806.2(i)

(3) Routine servicing as defined in § 806.2(l).

(4) Stock recovery as defined in § 806.2(m).

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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